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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,746	06/29/2001	Ronald J. Pettis	7767-173562	4733

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EXAMINER	
HAYES, MICHAEL J	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,746	PETTIS ET AL.	
	Examiner	Art Unit	
	Michael J. Hayes	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *97 and 98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65,67-72,74-77,79-82,85-88,90-93,96,99,101-106,108,109,111-116 and 118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 65,67-72,74-77,79-82,85-88,90-93,96-99,101-106,108,109,111-116 and 118.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 65, 67-71, 74-77, 79, 80, 81, 85-88, 90, 91, 92, 96, 99, 101-105, 108, 109, 111-115, and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS in view of D'Antonio et al. (US Patent No. 6,056,716) or Puri et al. (*An Investigation Of The Intradermal Route As An Effective Means Of Immunization For Microparticulate Vaccine Delivery Systems*, Vaccine 18 (2000) 2600-2612).

Gross discloses a method of delivering various drugs and medicine, including heparin intradermally (3:40-41) using a single needle with an outlet at a depth of 250 mm - 2mm in a controlled manner based on needle diameter (4:10-35). Gross discloses that the delivery can be infusion, pulsatile, or intermittent doses (col. 4, ll. 49-53) and that the dose rate can be varied as per the individual or drug type delivered needs (col. 4, ll. 55-57; col. 5, ll. 26-30, col. 8, ll. 13-15). Upon delivering medication to the intradermal compartment, the physiology of this location causes the improved systemic absorption as compared to bolus subcutaneous injections (see col. 3, ll. 38-44). Gross does not explicitly state that the delivery is by bolus administration; however, in view of the disclosure in Gross that delivery rates can be varied according to the patient's needs (see cite above) it would be obvious to one of ordinary skill in the art to deliver

the disclosed drugs via bolus administration. One of ordinary skill in the art would recognize that drug delivery can be bolus administration or infusion and that various drugs and patient conditions suggest different rates. Applicant recognizes the two common delivery rates of bolus and infusion in remarks received 9/26/05, pg. 9, first full paragraph, and that the difference between the two is delivery rate or time of delivery. In view of the different delivery rates that the prior art device can perform, one of ordinary skill would find obvious that the Gross disclosure, taken as a whole, suggests bolus administration as well as infusion rates.

Gross does not disclose that the intradermal delivery achieves improved systemic absorption relative to absorption upon injecting subcutaneously. D'Antonio (3:27-28, 29:3-26) and Puri (See abstract, pg. 2601, 2607-2610) suggest that medication delivered intradermally results in improved systemic absorption. D'Antonio teaches ID injections for growth hormones, vaccines, sera, vitamins, and nutrients. D'Antonio discloses that intradermal injection testing shows a better absorption than subcutaneous injection as evidenced by tests showing that ID is more potent than subcutaneous injections. Puri teaches better absorption by ID injections for microparticulate vaccines having better absorption than subcutaneous injections as evidenced by lower required doses when administered ID. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of D'Antonio and/or Puri in the method of Gross in order to achieve a therapeutic result using less drugs. The cost savings and ability to effectively deliver scarce drugs to a larger number of people would motivate one of ordinary skill in the art to modify the method of Gross with the teachings of D'Antonio and/or Puri.

The use of nanoparticles are considered as equivalent to the disclosed use of microparticles in the prior art, and obvious to give improved absorption, particularly in

consideration that the nanoparticles are even smaller than the microparticles. Additionally, in view of the large number and classes of drugs listed by Gross for delivery by the disclosed method, the use of dopamine receptor agonist would have been obvious to one of ordinary skill in the art because it is recognized as another similarly administered drug, intradermally or subcutaneously (See Gross, col. 6, line 41 - col. 7, line 20). It would be obvious to one of ordinary skill in the art to apply the prior art method to additional drugs in view of the teachings of broad applicability to different drugs.

Claims 72, 82, 93, 106, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS in view of D'ANTONIO or PURI as applied to claims 71, 77, 87, 105, or 115 above, and further in view of GANDERTON et al. (US Patent No. 3,814,097). Gross discloses the claimed method except for using an array of needles. Ganderton discloses injecting a substance through multiple needles (col. 1, ll. 9-40; fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ganderton in the method of Gross and D'Antonio or Puri in order to facilitate the distribution of larger quantities of delivered drug to a patient.

Response to Arguments

Applicant's arguments with respect to claims previously rejected under 35 USC 102 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues there is no suggestion to combine the teachings of the prior art references and that the combination of Gross and Puri or D'Antonio fail to suggest bolus administration to the intradermal space to achieve improved absorption over subcutaneous

injection. The examiner disagrees and discusses the suggestion of bolus administration to the intradermal space, as disclosed by Gross, above. Puri and D'Antonio address the delivery of drugs to patients and recognize improved absorption of intradermal delivery as compared to subcutaneous delivery. This disclosure is evidence of prior art knowledge of the improved absorption of intradermal injection, as compared to subcutaneous injection. If not an inherent effect of intradermal delivery, this disclosure in the prior art provides motivation one of ordinary skill in the art to deliver the drugs in this manner in order to more efficiently treat a patient, with smaller amounts of drug required. Puri and D'Antonio are concerned with the same problem confronted with Gross, that is, methods of administering drugs (i.e., body affecting agents) to a patient to achieve an appropriate dosage regime to fit the requirements of the patient and the drug.

The prior art references are the same as those used in the rejections under 35 USC 103 in the last office action. Though using the same references, they are presented in a new light, which view was prompted by the amendments submitted by Applicant in paper received 9/26/05.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SRIVASTAVA et al. (US Patent No. 6,007,821) discusses method of delivering intradermally, including bolus delivery, to use less quantities as compared to subcutaneous delivery, see col. 20, ll. 2-15.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons, can be contacted at (571) 272-4965. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
22 December 2005

MICHAEL J. HAYES
PRIMARY EXAMINER